



Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

Telephone: 301-402-5567
FAX: 301-402-2071
E-mail: mcarome@osophs.dhhs.gov

October 23, 2001

Francisco Cigarroa, M.D.
President
The University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, Texas 78229-3900

Frank F. Ledford, Jr., M.D., F.A.C.S.
President
Southwest Foundation for Biomedical Research
P.O. Box 760549
San Antonio, Texas 78245-0549

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA)
M-1403**

**Research Project: M. A. Escamilla, et al. A minimalist approach to gene mapping:
locating the gene for Acheiropodia, by homozygosity analysis. *Am J Hum Genet*
66:1995-2000; 2000.
NIH Project Numbers: K01 MH01453, R01 MH49499, and K02 MH01375**

Dear Dr. Cigarroa and Dr. Ledford:

The Office for Human Research Protections (OHRP) has reviewed your October 8, 2001 letter regarding the above-referenced research that was submitted in response to OHRP's August 28, 2001.

Based upon its review, OHRP finds that the University of Texas Health Science Center at San Antonio (UTHSC) and Southwest Foundation for Biomedical Research (SFBR) have implemented the required actions stipulated by OHRP's August 28, 2001 letter. In particular, OHRP acknowledges the following:

- (1) UTHSC and SFBR suspended the above referenced research immediately upon finding that it did not have IRB approval and the investigators were counseled at that

time. Furthermore, SFBR has issued a memorandum to all its investigators regarding the need for proper IRB review of human subject research, and implemented educational training regarding human subject research for investigators and other research staff.

(2) UTHSC and SFBR have provided a list of investigators and institutions involved in the conduct of the above referenced research.

(3) UTHSC and SFBR have conducted an audit of all nonexempt research involving human subjects and found all such research to have been reviewed and approved by the UTHSC IRB.

As a result, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Michael A. Carome, M.D.
Director, Division of Compliance Oversight

cc: Dr. Wayne P. Pierson, Director, IRB, UTHSC
Mr. Jose R. Coronado, Director, South Texas Veterans Health Care System
Dr. Charles A. Coltman, Jr., Medical Director, CTRC Research Foundation
Dr. Helen Hazuda, Chairperson, IRB, UTHSC
Dr. Michael Escamilla, UTHSC
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James McCormack, FDA
Dr. John Mather, Director, Office of Research Compliance and Assurance, Department of Veterans Affairs
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. George Gasparis, OHRP
Dr. Jeffrey Cohen, OHRP
Mr. Barry Bowman, OHRP